

Form Approved. O.M.B. No.		Approval Expires	
<div>U.S. Food and Drug Administration</div> <div>NOTIFICATION FOR A FOOD CONTACT SUBSTANCE FORMULATION</div> <div>NOT FOR NEW USES OF FOOD CONTACT SUBSTANCES</div>		AGENCY USE ONLY	
		Date of Receipt	
<div>When completed send this form and notification to</div> <div>NOTIFICATION CONTROL ASSISTANT OFFICE OF PREMARKET APPROVAL HFS-200 200 C STREET, SW WASHINGTON, D.C. 20204</div>			
Enter the total number of pages in the Premarket Notification		Date Effective (if effective)	PMF Number
GENERAL INSTRUCTIONS		PMF- <div></div> <div></div> <div></div> <div></div> <div></div> <div></div>	
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Part I — GENERAL INFORMATION

1a. Person
Submitting
Notice

Name of authorized official	Position

Company

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Mailing address (number and street)

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City, State, ZIP Code, Country

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Telephone No.

Fax No.

E-Mail Address

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☐ Please check here if E-Mail is your preferred method of communication.

b. Agent (if
applicable)

Name of authorized official	Position

Company

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Mailing address (number and street)

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City, State, ZIP Code, Country

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Telephone No.

Fax No.

E-Mail Address

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☐ Please check here if E-Mail is your preferred method of communication.

Section A - IDENTIFICATION OF THE FOOD CONTACT SUBSTANCE/FORMULATION

1. Chemical Identity

Trade or common names

2. Formulation Composition

number that authorizes use,

[illegible]

Part II — INFORMATION ON IDENTITY, USE AND EXPOSURE — Continued

Section A - IDENTIFICATION - Continued

b. Characterization

List those characteristics of the formulation necessary to verify that the formulation may be lawfully marketed.

Polymer Properties	Values

c. Describe the manufacturing process, including times and temperatures, and include chemical equations for all synthetic steps and side reactions. Describe any purification steps.

☐ Mark (X) this box if you attach a continuation sheet.

Part III — INTENDED USE

1. Describe the intended use of the food contact substance formulation, including maximum use levels (or thickness) in food contact materials, and types of food contact articles in which it is expected to be used (e.g., films, coatings, molded articles). State whether single or repeated use is intended. Provide maximum temperatures and times of food contact, refer to classifications in 21 CFR 176.170© Table 2 when possible.

☐ Please check here if you attach a continuation sheet.

2. List types of food expected to contact the formulation, with examples if known. Refer to classifications in 21 CFR 176.170(c) Table 1 when possible.

☐ Please check here if you attach a continuation sheet.

PHYSICAL AND CHEMICAL PROPERTIES WORKSHEET

To assist FDA's review of physical and chemical properties data, please complete the following worksheet for data you provide and include it in the notification. Identify the property measured, the page of the notification on which the property appears, the value of the property, and the units in which the property is measured (as necessary). The measured properties should be for the food contact substance formulation. You are not required to submit this worksheet.

Property (a)	Mark (X) if provided	Page number (b)	Value ©	Measured or Estimate (M or E)
Physical state of the substance	<input type="checkbox"/>		<input type="checkbox"/> (s) <input type="checkbox"/> (l) <input type="checkbox"/> (g)	
Vapor pressure @ Temperature <input type="text"/> °C	<input type="checkbox"/>		<input type="text"/> Torr	
Density/relative density (specify temperature)	<input type="checkbox"/>		<input type="text"/> g/cm3	
Solubility @ Temperature <input type="text"/> °C Solvent <input type="text"/>	<input type="checkbox"/>		<input type="text"/> g/L	
Solubility in water @ Temperature <input type="text"/> °C	<input type="checkbox"/>		<input type="text"/> g/L	
Melting Temperature	<input type="checkbox"/>		<input type="text"/> °C	
Boiling/sublimation temperature @ <input type="text"/> torr pressure	<input type="checkbox"/>		<input type="text"/> °C	
Spectra	<input type="checkbox"/>		<input type="text"/>	
Dissociation constant	<input type="checkbox"/>		<input type="text"/>	
Particle size distribution	<input type="checkbox"/>		<input type="text"/>	
Octanol/water partition coefficient	<input type="checkbox"/>		<input type="text"/>	
Henry's Law constant	<input type="checkbox"/>		<input type="text"/>	
pH <input type="text"/> @ concentration <input type="text"/>	<input type="checkbox"/>		<input type="text"/>	
Adsorption/coefficient	<input type="checkbox"/>		<input type="text"/>	
Other - Specify <input type="text"/>	<input type="checkbox"/>		<input type="text"/>	
Polymer specific (If a range is applicable, indicate so) % crystallinity of polymer	<input type="checkbox"/>		<input type="text"/>	
Degree of orientation	<input type="checkbox"/>		<input type="text"/>	
Thermal transitions of polymer (i.e., Tg, Tm)	<input type="checkbox"/>		<input type="text"/>	
Density of polymer (specify temperature)	<input type="checkbox"/>		<input type="text"/>	
<input type="text"/>	<input type="checkbox"/>		<input type="text"/>	

Part IV — LIST OF ATTACHMENTS

Attach continuation sheets for sections of the form and test data and other data (including physical/chemical properties and structure/activity information), and optional information after this page. Clearly identify the attachment and the section of the form to which it relates, if appropriate. Number consecutively the pages of the attachments. In the column below, enter the inclusive page numbers of each attachment. Notifiers need not list other components of their notification not specifically referenced to this form.

[illegible]

☐ Mark (X) this box if you attach a continuation sheet. Enter the attachment name and number.